K103221

510(k) Summary

DEC 2 8 2010

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name and Contact Information

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Date Prepared: October 29, 2010

Device Name

Proprietary name:	(1) Elecsys hGH CalSet (2) Elecsys hGH CalCheck 5
Common name:	(1) hGH CalSet (2) hGH CalCheck 5
Classification name:	(1) Calibrator, secondary (2) Single (specified) analyte controls (assayed and unassayed)

Predicate Devices

The Elecsys hGH CalSet is substantially equivalent to other products in commercial distribution for similar use. We claim equivalency to the current marketed Elecsys C-Peptide CalSet (K033873).

The Elecsys hGH CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys C-Peptide CalCheck 5 (K100810).

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510(k) Summary, Continued

Device Description

The Elecsys hGH CalSet and hGH CalCheck 5 are lyophilized products consisting of human growth hormone (hGH) in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended Use

The Elecsys hGH CalSet is used for calibrating the quantitative Elecsys hGH assay on the Elecsys and **cobas e** immunoassay analyzers.

The Elecsys hGH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys hGH reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Comparison Tables

The tables below compare the Elecsys hGH CalSet and Elecsys hGH CalCheck 5 with their predicate devices, Elecsys C-Peptide CalSet (K033873) and Elecsys C-Peptide CalCheck 5 (K100810), respectively.

Table 1. Elecsys hGH CalSet Comparison Table

Characteristic	Elecsys hGH CalSet (Candidate Device)	Elecsys C-Peptide CalSet (K033873)
Intended Use	Elecsys hGH CalSet is used for calibrating the quantitative Elecsys hGH assay on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys C-Peptide CalSet is used for calibrating the quantitative Elecsys C-Peptide assay on the Elecsys and **cobas e** immunoassay analyzers.
Analyte	Human growth hormone (hGH)	C-Peptide
Levels	Two	Same
Format	Lyophilized	Same
Handling	Add exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Same
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • -20°C: 28 days (freeze only once) • On Elecsys 2010 and **cobas e** 411 (20-25 °C): Up to 5 hours • On MODULAR ANALYTICS E170, **cobas e** 601, and **cobas e** 602: Use only once.	Unopened: • Same Reconstituted: • -20°C: 1 month (freeze only once) • On analyzers (20-25 °C): Use only once.
Matrix	Human serum matrix	Equine serum matrix

Continued on next page

Comparison Tables, continued

Table 2. Elecsys hGH CalCheck 5 Comparison Table

Characteristic	Elecsys hGH CalCheck 5 (Candidate Device)	Elecsys C-Peptide CalCheck 5 (K100810)
Intended Use	The Elecsys hGH Calcheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys hGH reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	The Elecsys C-Peptide CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys C-Peptide reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Analyte	Human growth hormone (hGH)	C-Peptide
Levels	Five	Same
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Same
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20-25°C: 5 hours	Unopened: • Same Reconstituted: • 20-25°C: 4 hours
Matrix	Human serum matrix	Equine serum matrix

Performance Characteristics

The Elecsys hGH CalSet and Elecsys hGH CalCheck 5 were evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Roche Diagnostics
c/o Ms. Kelly Collen O'Maine Adams
Regulatory Affairs Specialist
9115 Hague Road, P.O. Box 50416
Indianapolis, IN 46250-0416

Re: k103221
Trade Name: The Elecsys hGH CalSet, The Elecsys hGH CalCheck 5
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT, JJX
Dated: October 29, 2010
Received: November 01, 2010

DEC 2 3 2010

Dear Ms. O'Maine Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

K103221

510(k) Number (if known):

DEC 23 2010

Device Name: Elecsys hGH CalSet

Indication For Use:

Elecsys hGH CalSet is used for calibrating the quantitative Elecsys hGH assay on the Elecsys and **cobas e** immunoassay analyzers.

Prescription Use __X____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indication for Use

DEC 2 3 2010

510(k) Number (if known):

Device Name: Elecsys hGH CalCheck 5

Indication For Use:

The Elecsys hGH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys hGH reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
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